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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,975	07/03/2003	Donald L. Wise	CSI 130	8618

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,975	WISE ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-21 are pending in this application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 are, drawn to a vaccine composition, classified in class 424, subclass 184.1.

II. Claims 12-19 are, drawn to a porous particulate formulation, classified in class 424, subclass 278.1.

III. Claims 20-21 are, drawn to a method of inducing immune response, classified in class 435, subclass 69.3.

3. The inventions are distinct, each from the other because of the following reasons:

Claims of group I and II are drawn to structurally and functionally different distinct compositions and those of group III are drawn to a method.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the one can use a different vaccine composition to induce an immune response against a pathogen.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the porous formulation can be used for drug delivery.

4. During a telephone conversation with Attorney Patrea L. Pabst (reg # 31284) on 12/10/2003 a provisional election was made with traverse to prosecute the invention of group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. During a telephone conversation with Attorney Patrea L. Pabst (reg # 31284) on 12/10/2003, Attorney Pabst mentioned submitting of an Information Disclosure Statement on October of 2003. However, at this time there is no record of said IDS, which has been matched with this application. The Examiner notified Attorney Pabst of this issue. The examiner will respectfully notify the applicants in future if any further information submitted to the examiner in regard to said IDS.

Abstract

7. The abstract of the disclosure is objected to because of the use of abbreviations ODNs and CPG. Full name of said abbreviations are required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition inducing immune response against certain pathogens, does not reasonably provide enablement for a vaccine for inducing immune response against all pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case claims 1-11 are very broad and drawn to a vaccine. The only given example in the specification is in pages 11 and 14, mentioning the production of antigens for certain species of malaria and anthrax.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicants' invention is not enabled for the prevention, amelioration, or treatment of infectious diseases. And one skilled in the art will not be able to make/and or use the invention without undue experimentation commensurate in scope with the claims.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 5, 6, 7 and 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "approximately" in claim 6 is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is not clear what constitute the metes and bounds of " less than five micron" in claims 5 and 7. The term less than five constitute any diameter between 0-4.99 micron.

It is not clear what constitute the metes and bounds of " ultrahigh pressures" in claim 6.

Claim 9 is reciting the abbreviation *H.pylori.* Full name of said abbreviation is required when it appears in claim for the first time.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Hagan Derek (Journal of Pharmacy and Pharmacology, Vol. 50, No. 1, pp.1-10, 1998).

The claims are drawn a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen in a biodegradable polymer.

O'Hagan Derek teaches a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen in a biodegradable polymer (see abstract). O'Hagan teaches poly (lactide-co-glycolide) a biodegradable polymer (page 6). O'Hagan teaches a variety of pathogens including malaria and *Helicobacter pylori* (**see** pages 2 and 3). O'Hagan teaches encapsulation (page6), adjuvants (page 5) particulates less than 5 micron and greater than 10 micron (see page 6). O'Hagan teaches mucosal immunization including nasal and oral (page 4). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants'

composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed composition and the composition of the prior art (i. e., that the composition of prior art does not possess the same material structure and functional characteristics of the claimed composition). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan et al. (Molecular Medicine Today, February 1997) in view of Seagar (US patent application US 2002/0197321 A1) and further in view of Flick –Smith et al. (Infection and Immunity Vol. 70, No.4, pp. 2022-2028, April 2002).

The claims are drawn a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen in a biodegradable polymer.

O'Hagan et al. teach a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen in a biodegradable polymer (see abstract). O'Hagan et al. teach poly (lactide-co-glycolide) a biodegradable polymer (page 70). O'Hagan et al. teach a variety of pathogens including malaria (**see** pages 69, 72 and 73). O'Hagan et al. teach encapsulation (page 73), adjuvants (page 72) a particulate less than 5

micron and (see page 69). O'Hagan et al. teach mucosal immunization including nasal and oral (page 69). O'Hagan et al. do not teach *anthrax*. However, Flick –Smith et al. teach mucosal or parental administration of microsphere associated *Bacillus anthrax* protective antigen against *anthrax* infection in mice (see title and abstract). Flick –Smith et al. teach the formation of biodegradable polymer by lyophilization (see page 2023). Flick –Smith et al. do not teach extruding or cryogenically forming of the matrix. However Seager teaches extruding, frozen suspension and spray chilling of the matrix (see claims).

It would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of O'Hagan et al. with the teachings Flick –Smith et al. and Seager to obtain the claimed invention. One of ordinary skill in the art would have been motivated by the teachings O'Hagan et al. to use polymeric microparticles to enhance immunogenicity of DNA vaccines.

Conclusions

16. No claim is allowed.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kim et al. Helicobacter, Vol. 4, No. 1, 1999.

Ren et al. World Journal of Gastroenterology, Vol. 8, No. 6, 2002.

Park et al. Experimental and Molecular Medicine, Vol. 32, No. 2, 2000.

Kim et al. Vaccine, Vol. 17, 1999.

Rafati et al. Vaccine, Vol. 15, No. 17/18 1997.

O'Hagan et al. (US 6,306,405) 2001.

O'Hagan et al. (US 6,086,901) 2000

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

December 12, 2003